Commissioner for the Department for Medicaid Services
Selections for Preferred Products

This is a summary of the final Preferred Drug List (PDL) selections made by the Commissioner for the Department for Medicaid Services based on the Drug Review Options submitted to the Pharmacy and Therapeutics (P&T) Advisory Committee for review on September 17, 2015.

Description of Recommendation	Final Decision (s)
New Products to Market: Orkambi® Lumacaftor-ivacaftor (Orkambi®) will be approved: • Initially (6 months) if ALL of the following criteria are met: o Age ≥ 12 years; AND o Diagnosis of cystic fibrosis homozygous for the F508del mutation in the CFTR gene confirmed by an FDA-cleared CF mutation test; AND o Baseline FEV_1 between 40-90%; serum transaminases < 3x ULN and bilirubin < 2x ULN; AND o Baseline ophthalmic examinations if patient is 12 to 18 years of age. • For continuation of therapy if ALL of the following criteria are met: o Stable or improved FEV_1 ; AND o Serum ALT or AST ≤5 x upper limit of normal (ULN), or ALT or AST ≤3 x ULN with bilirubin ≤2 x ULN.	The final PDL placement will be determined after a review of this product at a future P&T meeting.
New Products to Market: Stiolto™ Respimat® Place this product non preferred with similar quantity limits in the PDL class titled COPD Agents.	Stiolto™ Respimat® will be placed non preferred with similar quantity limits in the PDL class titled COPD Agents.

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New Products to Market: Entresto™ Place this product non preferred in the PDL class titled Angiotensin Receptor Blockers; however, approve Entresto™ if ALL of the following criteria are met: • Age ≥ 18 years ; AND • Diagnosis of chronic heart failure (NYHA Class II-IV); AND • Left ventricular ejection fraction ≤ 40%; AND • No history of angioedema related to previous ACE inhibitor or ARB therapy; AND • No use of an ACE inhibitor within 36 hours of starting sacubitril/valsartan or during therapy; AND • Patient does NOT have diabetes and taking aliskiren; AND • Patient is NOT pregnant.	Entresto™ will be placed non preferred in the PDL class titled Angiotensin Receptor Blockers; however, Entresto™ will be approved if ALL of the following criteria are met: • Age ≥ 18 years ; AND • Diagnosis of chronic heart failure (NYHA Class II-IV); AND • Left ventricular ejection fraction ≤ 40%; AND • No history of angioedema related to previous ACE inhibitor or ARB therapy; AND • No use of an ACE inhibitor within 36 hours of starting sacubitril/valsartan or during therapy; AND • Patient does NOT have diabetes and taking aliskiren; AND • Patient is NOT pregnant.
Oral Oncology, Renal Cell Carcinoma 1. DMS to select preferred agent(s) based on economic evaluation; however, at least one oral agent representing a Category 1 recommendation by the NCCN for each cancer type should be preferred. 2. Continue quantity limits based on FDA-approved maximum dose. 3. Agents not selected as preferred will be considered non preferred and require PA. 4. DMS to allow continuation of therapy for existing users of non preferred single-source branded products via a 90 day look back. 5. For any new chemical entity in the Oral Oncology, Renal Cell Carcinoma class, require a PA until reviewed by the P&T Advisory Committee.	**Selected Preferred Agent (s)** Afinitor® Nexavar® Sutent® Votrient® **Non Preferred Agent (s)** Afinitor Disperz® Inlyta®

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Oral Oncology, Prostate Cancer 1. DMS to select preferred agent(s) based on economic evaluation; however, at least one oral agent representing a Category 1 recommendation by the NCCN for each cancer type should be preferred. 2. Continue quantity limits based on FDA-approved maximum dose. 3. Agents not selected as preferred will be considered non preferred and require PA. 4. DMS to allow continuation of therapy for existing users of non preferred single-source branded products via a 90 day look back. 5. For any new chemical entity in the Oral Oncology, Prostate Cancer class, require a PA until reviewed by the P&T Advisory Committee.	**Selected Preferred Agent (s)** bicalutamide flutamide Xtandi® Zytiga® **Non Preferred Agent (s)** Casodex® Eulexin® Nilandron®
Alzheimer's Agents 1. DMS to select preferred agent (s) based on economic evaluation; however, at least one single-entity acetylcholinesterase inhibitor and one single-entity NMDA receptor antagonist should be preferred. 2. Agents not selected as preferred will be considered non-preferred and will require Prior Authorization. 3. For any new chemical entity in the Alzheimer's Agents class, require a PA until reviewed by the P&T Advisory Committee.	**Selected Preferred Agent (s)** donepezil 5, 10 mg Exelon® Patches memantine rivastigmine capsules **Non Preferred Agent (s)** Aricept® donepezil ODT, 23 mg Exelon® Capsules galantamine galantamine ER Namzaric® Namenda® Namenda® XR Razadyne® Razadyne ER® rivastigmine patches
Antialcoholic Preparations 1. DMS to select preferred agent(s) based upon economic evaluation; however, at least two unique chemical entities, one of which should be intramuscular naltrexone, should be preferred. 2. Agents not selected as preferred will be considered non-preferred and will require Prior Authorization. 3. Any new chemical entity in the Antialcoholic Preparations class should require a PA until reviewed by the P&T Advisory Committee.	**Selected Preferred Agent (s)** naltrexone Vivitrol® **Non Preferred Agent (s)** acamprosate Antabuse® disulfiram ReVia®

Description of Recommendation	Final Decision (s)
Anxiolytics 1. DMS to select preferred agent(s) based upon economic evaluation; however, at least five unique chemical entities, one of which is not a controlled substance, should be preferred. 2. Agents not selected as preferred will be considered non-preferred and will require Prior Authorization. 3. Any new chemical entity in the Anxiolytics class should require a PA until reviewed by the P&T Advisory Committee.	**Selected Preferred Agent (s)** alprazolam tablets, intensol buspirone chlordiazepoxide clorazepate diazepam lorazepam oxazepam **Non Preferred Agent (s)** alprazolam ER alprazolam ODT Ativan® meprobamate Tranxene-T® Valium® Xanax® Xanax ER®
Anxiolytic Duration Edit Benzodiazepines, with the exception of clonazepam, will be available without requiring a prior authorization for the initial 60 days per year. For therapy beyond 60 days, prior authorization will be required and approved as follows: • Request must come from the physician; AND • Approve for 6 months for the following diagnoses: o Anxiety; or o Anxiety disorder; or o Panic attacks/disorder; or o Agoraphobia; or o Social phobia; or o Depression; or o Chemotherapy-induced nausea & vomiting; or o Status epilepticus; OR • Approve for 1 month for a diagnosis of acute alcohol withdrawal; OR • Approve for 1 year for a diagnosis of seizures.	Benzodiazepines, with the exception of clonazepam, will be available without requiring a prior authorization for the initial 60 days per year. For therapy beyond 60 days, prior authorization will be required and approved as follows: • Request must come from the physician; AND • Approve for 6 months for the following diagnoses: o Anxiety; or o Anxiety disorder; or o Panic attacks/disorder; or o Agoraphobia; or o Social phobia; or o Depression; or o Chemotherapy-induced nausea & vomiting; or o Status epilepticus; OR • Approve for 1 month for a diagnosis of acute alcohol withdrawal; OR • Approve for 1 year for a diagnosis of seizures.

Description of Recommendation	Final Decision (s)
Monoamine Oxidase Inhibitors (MAOIs) 1. DMS to select preferred agent(s) based upon economic evaluation. 2. Agents not selected as preferred will be considered non-preferred and will require Prior Authorization. 3. Any new chemical entity in the Monoamine Oxidase Inhibitors class should require a PA until reviewed by the P&T Advisory Committee.	**Selected Preferred Agent (s)** N/A **Non Preferred Agent (s)** Emsam® Marplan® Nardil® Parnate® phenelzine tranylcypromine
Antidepressants, Other 1. DMS to select preferred agent(s) based upon economic evaluation; however, at least bupropion and trazodone should be preferred. 2. Agents not selected as preferred will be considered non-preferred and will require Prior Authorization. 3. Any new chemical entity in the Antidepressants, Other class should require a PA until reviewed by the P&T Advisory Committee.	**Selected Preferred Agent (s)** bupropion bupropion XL bupropion SR trazodone **Non Preferred Agent (s)** Aplenzin™ Brintellix™ Forfivo XL™ nefazodone Oleptro™ Viibryd™ Wellbutrin® Wellbutrin® XL Wellbutrin® SR
Selective Norepinephrine Reuptake Inhibitors (SNRIs) 1. DMS to select preferred agent(s) based upon economic evaluation; however, at least one long acting SNRI should be preferred. 2. Agents not selected as preferred will be considered non-preferred and will require Prior Authorization. 3. For any new chemical entity in the Selective Norepinephrine Reuptake Inhibitors (SNRIs) class, require a PA until reviewed by the P&T Advisory Committee.	**Selected Preferred Agent (s)** Pristiq® Savella™ venlafaxine venlafaxine ER capsules **Non Preferred Agent (s)** Cymbalta® desvenlafaxine ER base desvenlafaxine fumarate ER duloxetine duloxetine delayed release Effexor XR® Fetzima™ Irenka™ Khedezla® venlafaxine ER tablets

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Milnacipran (Savella™) Clinical Criteria Milnacipran (Savella™) will be approved for a diagnosis of fibromyalgia only.	Milnacipran (Savella™) will be approved for a diagnosis of fibromyalgia only.
Duloxetine Clinical Criteria Duloxetine will be approved for the following diagnoses: • Depression/Major Depressive Disorder/Generalized Anxiety Disorder/Social Anxiety Disorder/Panic Disorder: Approval after trial and failure of or intolerance or contraindication to one preferred SNRI; OR • Diabetic peripheral neuropathic pain; OR • Fibromyalgia; OR • Chronic musculoskeletal pain: Approval after trial and failure of or intolerance or contraindication to one NSAID.	Duloxetine will be approved for the following diagnoses: • Depression/Major Depressive Disorder/Generalized Anxiety Disorder/Social Anxiety Disorder/Panic Disorder: Approval after trial and failure of or intolerance or contraindication to one preferred SNRI; OR • Diabetic peripheral neuropathic pain; OR • Fibromyalgia; OR • Chronic musculoskeletal pain: Approval after trial and failure of or intolerance or contraindication to one NSAID.
Selective Serotonin Reuptake Inhibitors (SSRIs) 1. DMS to select preferred agent(s) based upon economic evaluation; however, at least four unique chemical entities should be preferred. 2. Agents not selected as preferred will be considered non-preferred and will require Prior Authorization. 3. Any new chemical entity in the Selective Serotonin Reuptake Inhibitors (SSRI) class should require a PA until reviewed by the P&T Advisory Committee.	**Selected Preferred Agent (s)** citalopram escitalopram tablets fluoxetine capsules, solution fluoxetine ER paroxetine sertraline **Non Preferred Agent (s)** Brisdelle™ Celexa® escitalopram solution fluoxetine 90 mg DR, tablets fluvoxamine fluvoxamine ER Lexapro™ paroxetine controlled release Paxil® Paxil® CR Pexeva® Prozac® Prozac Weekly™ Sarafem® Zoloft®

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<u>Tricyclic Antidepressants</u> 1. DMS to select preferred agent(s) based upon economic evaluation; however, at least four unique chemical entities should be preferred. 2. Agents not selected as preferred will be considered non-preferred and will require Prior Authorization. 3. For any new chemical entity in the Tricyclic Antidepressants class, require a PA until reviewed by the P&T Advisory Committee.	**Selected Preferred Agent (s)** amitriptyline clomipramine desipramine imipramine maprotiline mirtazapine nortriptyline **Non Preferred Agent (s)** Anafranil® amoxapine doxepin imipramine pamoate Norpramin® Pamelor® protriptyline Remeron® Silenor® Tofranil® Tofranil-PM® Surmontil®

Description of Recommendation	Final Decision (s)
First-Generation Anticonvulsants 1. DMS to select preferred agent (s) based on economic evaluation; however, at least six unique chemical entities should be preferred. 2. Agents not selected as preferred will be considered non preferred and require prior authorization. 3. For any agent not selected as preferred, DMS to allow continuation of therapy if there is a paid claim in the past 90 days. 4. For any new chemical entity in the First-Generation Anticonvulsants class, require a PA until reviewed by the P&T Advisory Committee.	**Selected Preferred Agent (s)** Celontin® clonazepam tablets Depakote® Sprinkle DiaStat® divalproex delayed-release ethosuximide felbamate Peganone® phenobarbital Phenytek® phenytoin IR/ER primidone valproate valproic acid **Non Preferred Agent (s)** clonazepam ODT Depakene® Depakote® Depakote ER® diazepam rectal gel Dilantin® divalproex sprinkle divalproex sodium extended-release Felbatol® Klonopin® Mysoline® Onfi™ Stavzor™ Zarontin®
Clobazam (Onfi™) Clinical Criteria Clobazam (Onfi™) will be approved for the following diagnoses: • Lennox-Gastaut Syndrome; OR • Seizure disorder after trial and failure of one anticonvulsant.	Clobazam (Onfi™) will be approved for the following diagnoses: • Lennox-Gastaut Syndrome; OR • Seizure disorder after trial and failure of one anticonvulsant.

Description of Recommendation	Final Decision (s)
Second-Generation Anticonvulsants 1. DMS to select preferred agent (s) based on economic evaluation; however, at least seven unique chemical entities should be preferred. 2. Agents not selected as preferred will be considered non preferred and require prior authorization. 3. For any agent not selected as preferred, DMS to allow continuation of therapy if there is a paid claim in the past 90 days. 4. For any new chemical entity in the Second-Generation Anticonvulsants class, require a PA until reviewed by the P&T Advisory Committee.	**Selected Preferred Agent (s)** Banzel™ Gabitril® gabapentin capsules, solution lamotrigine IR tablets, ODT levetiracetam IR Lyrica® Sabril® topiramate IR zonisamide **Non Preferred Agent (s)** Fycompa™ gabapentin tablets Gralise™ Keppra™ Keppra XR™ Lamictal® Lamictal® XR lamotrigine ER lamotrigine ODT levetiracetam ER Neurontin® Potiga® Qudexy XR™ tiagabine Topamax® topiramate ER Trokendi XR™ Vimpat® Zonegran®
Rufinamide (Banzel™) Clinical Criteria Rufinamide (Banzel™) will be approved for the following diagnoses: • Lennox-Gastaut Syndrome; OR • Seizure disorder after trial and failure of one anticonvulsant.	Rufinamide (Banzel™) will be approved for the following diagnoses: • Lennox-Gastaut Syndrome; OR • Seizure disorder after trial and failure of one anticonvulsant.

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Pregabalin (Lyrica®) Clinical Criteria Pregabalin (Lyrica®) will be approved for the following diagnoses: • Diabetic Peripheral Neuropathy (DPN); OR • Neuropathic pain associated with spinal cord injury; OR • Postherpetic Neuralgia (PHN) AFTER adequate trial and failure of at least one of these first-line agents: o Tricyclic antidepressant (TCAs); or o Anticonvulsant: gabapentin; or o Topical: Lidocaine 5% patch; OR • Adjunct for partial onset seizure disorder; OR • Fibromyalgia	Pregabalin (Lyrica®) will be approved for the following diagnoses: • Diabetic Peripheral Neuropathy (DPN); OR • Neuropathic pain associated with spinal cord injury; OR • Postherpetic Neuralgia (PHN) AFTER adequate trial and failure of at least one of these first-line agents: o Tricyclic antidepressant (TCAs); or o Anticonvulsant: gabapentin; or o Topical: Lidocaine 5% patch; OR • Adjunct for partial onset seizure disorder; OR • Fibromyalgia
Vigabatrin (Sabril®) Clinical Criteria Vigabatrin (Sabril®) will be approved for the following diagnoses: • Infantile spasms; OR • Seizure disorder after trial and failure of one anticonvulsant.	Vigabatrin (Sabril®) will be approved for the following diagnoses: • Infantile spasms; OR • Seizure disorder after trial and failure of one anticonvulsant.
Carbamazepine Derivatives 1. DMS to select preferred agent (s) based on economic evaluation; however, at least two unique chemical entities should be preferred. 2. Agents not selected as preferred will be considered non preferred and require prior authorization. 3. For any agent not selected as preferred, DMS to allow continuation of therapy if there is a paid claim in the past 90 days. 4. For any new chemical entity in the Anticonvulsants, Carbamazepine Derivatives class, require a PA until reviewed by the P&T Advisory Committee.	**Selected Preferred Agent (s)** Carbatrol® carbamazepine carbamazepine extended-release Equetro™ oxcarbazepine **Non Preferred Agent (s)** Aptiom® carbamazepine extended-release (Generic Carbatrol®) Epitol® Oxtellar™ XR Tegretol® Tegretol® XR Trileptal®

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Gabapentin Enacarbil (Horizant™) Clinical Criteria Gabapentin enacarbil (Horizant™) will be approved for the following diagnoses: • Restless leg syndrome after trial and failure of **ONE** of the following: o Levodopa/Carbidopa; **or** o Pramipexole; **or** o Ropinirole; **OR** • Postherpetic neuralgia	Gabapentin enacarbil (Horizant™) will be approved for the following diagnoses: • Restless leg syndrome after trial and failure of **ONE** of the following: o Levodopa/Carbidopa; **or** o Pramipexole; **or** o Ropinirole; **OR** • Postherpetic neuralgia
Lidocaine Patch Clinical Criteria Lidocaine patches will be approved for the following diagnoses: • Diagnosis of Post Herpetic Neuralgia; OR • Diagnosis of neuropathic pain after trial and failure of one agent in **ANY** of the following medication classes: o Tricyclic antidepressant; or o Anticonvulsant; or o SNRI	Lidocaine patches will be approved for the following diagnoses: • Diagnosis of Post Herpetic Neuralgia; OR • Diagnosis of neuropathic pain after trial and failure of one agent in **ANY** of the following medication classes: o Tricyclic antidepressant; or o Anticonvulsant; or o SNRI
Capsaicin Patches (Qutenza®) Clinical Criteria Capsaicin Patches (Qutenza®) will be approved for a diagnosis of postherpetic neuralgia after trial and failure of one of the following agents: • Gabapentin; OR • Pregabalin; OR • Lidocaine transdermal patches; OR • A tricyclic antidepressant.	Capsaicin Patches (Qutenza®) will be approved for a diagnosis of postherpetic neuralgia after trial and failure of one of the following agents: • Gabapentin; OR • Pregabalin; OR • Lidocaine transdermal patches; OR • A tricyclic antidepressant.
Paroxetine Mesylate (Brisdelle™) Clinical Criteria Paroxetine mesylate (Brisdelle™) will be approved for patients meeting ALL of the following criteria: • Diagnosis of moderate to severe vasomotor symptoms associated with menopause; AND • Patient is post-menopausal; AND • Trial and failure of or contraindication to ONE of the following: o Hormonal therapy (Examples: Premarin, Menest, Estrace, Prempro, Premphase, etc.); or o Other antidepressants (Examples: venlafaxine, other formulations of paroxetine, other SSRIs, etc.).	Paroxetine mesylate (Brisdelle™) will be approved for patients meeting ALL of the following criteria: • Diagnosis of moderate to severe vasomotor symptoms associated with menopause; AND • Patient is post-menopausal; AND • Trial and failure of or contraindication to ONE of the following: o Hormonal therapy (Examples: Premarin, Menest, Estrace, Prempro, Premphase, etc.); or o Other antidepressants (Examples: venlafaxine, other formulations of paroxetine, other SSRIs, etc.).